
First Californian Enrolls in Clinical Trial Funded by State Stem Cell Agency

Posted: September 20, 2011

First Californian Enrolls in Clinical Trial Funded by State Stem Cell Agency

San Francisco, Calif.—On September 17 the first patient was enrolled in a clinical trial funded in part by the California Institute for Regenerative Medicine (CIRM), the state stem cell agency. The trial is testing an investigational therapy derived from embryonic stem cells in patients with spinal cord injury, marking a milestone in CIRM's progress from funding basic discoveries to clinical research.

The patient was the fourth nation-wide enrolled in the trial run by Menlo Park-based Geron, Corp, which developed and produced the cells being tested in the clinical trial. Stanford University School of Medicine's Gary Steinberg performed the surgery at Santa Clara Valley Medical Center(SCVMC).

"When the people of California voted in favor of Proposition 71 they did so with the hope of seeing stem cell-based therapies for chronic disease and injuries. This first California patient to participate in Geron's landmark spinal cord injury trial is a major step toward fulfilling that hope," said Jonathan Thomas, chair of the CIRM governing board. "We are proud to be providing funding for this first safety trial, which is a critical step toward making safe and effective stem cell-based therapies available to patients."

Two of the prior patients received the cells at the Shepard Center in Atlanta and the third received the cells at Northwestern Memorial Hospital. The Phase 1, Food and Drug Administration-approved trial is designed to test the safety of the cell injections, not their effectiveness, and plans to enroll 10 patients.

Researchers at Geron worked with colleagues in Hans Keirstead's laboratory at University of California-Irvine to develop a way of maturing human embryonic stem cells into a cell type that they thought could repair injured spinal cords. Those cells, called oligodendrocyte precursors, were expected to further mature into the tissues that wrap around and protect neurons in the spine. This protective layer, called myelin, is often damaged in spinal cord injury.

"This clinical trial is a testament to the value of supporting all stages of research, which is CIRM's strategy," said Alan Trounson, president of the stem cell agency. "It took considerable basic research to understand how to coax embryonic stem cells into choosing the path to nerve cells and to oligodendrocytes in particular. Similarly, the toxicity testing in animal models and other preclinical research were all critical parts of the pathway to this clinical trial. CIRM now funds all these stages."

During the procedure, Steinberg injected about 2 million of the cells directly into the injured area of the patient's spinal cord, and the patient is doing well. Eligible patients must be within 14 days of their injury and the injury has to be to a specific region in the middle section of the spine.

About CIRM: CIRM was established in November 2004 with the passage of Proposition 71, the California Stem Cell Research and Cures Act. The statewide ballot measure, which provided \$3 billion in funding for stem cell research at California universities and research institutions, was overwhelmingly approved by voters, and called for the establishment of an entity to make grants and provide loans for stem cell research, research facilities, and other vital research opportunities. A list of grants and loans awarded to date may be seen [here](#): /grants

Source URL: <https://www.cirm.ca.gov/about-cirm/newsroom/press-releases/09202011/first-californian-enrolls-clinical-trial-funded-state>